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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC
This Document Relates to: Lisa Hyde, et al. v. C. R. Bard, Inc., et al. CV-16-00893-PHX-DGC	**DEFENDANTS' MOTION *IN LIMINE* NO. 6 TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT INFORMED CONSENT** (Assigned to the Honorable David G. Campbell)

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Bard moves *in limine* to exclude evidence and argument about informed consent by respectfully showing the Court as follows:

The plaintiffs' experts have offered opinions that Bard needed to provide the medical community with additional information about its IVC filters so that physicians could obtain informed consent from patients undergoing treatment with an IVC filter. These opinions were solely relevant (if at all) to the plaintiffs' failure-to-warn claims (Counts II and VII). Because those claims are no longer in the case, however, the Court should exclude opinions about what information is necessary from Bard to obtain informed consent.

FACTS

Several of the plaintiffs' experts offer opinions that Bard needed to provide the medical community with information contained in Bard's internal documents so that physicians could obtain informed consent from patients. For example, Drs. Kinney, Roberts, Kalva, and Hurst dedicate sections of their Rule 26 Reports to the concept of "informed consent" and their opinions that Bard should have conveyed additional information to physicians about its IVC filters because the physicians needed the information to obtain informed consent from their patients. (*See, e.g.*, Rule 26 Rep. of Drs. Kinney, Roberts, and Kalva, Mar. 6, 2017, at 7, 9-11, 19, 113-14 ("open, honest and complete performance, safety and complaint data from manufacturers are required for physicians to fulfill their standard of care responsibility to provide informed consent to their patients"), excerpts attached as Exhibit A; Rule 26 Rep. of Dr. Hurst regarding L. Hyde, June 5, 2017, at 6-8 (discussing informed consent and Dr. Hurst's opinion that Bard provide additional information so that physicians can pass along the information to patients), excerpts attached as Exhibit B.[1])

Likewise, the plaintiffs' counsel have elicited testimony from their expert

[1] Portions of Exhibits A and B that do not bear on the resolution of Bard's Motion and that either quote Bard internal documents or recount Ms. Hyde's medical care, have been redacted.

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witnesses during trial regarding information that they believe is necessary to obtain informed consent. For example, in response to a question during the *Jones* Trial about whether Dr. Muehrcke would have wanted to know certain internal Bard information, Dr. Muehrcke testified "Absolutely. Because when I go to put a filter in the patient I have to obtain an informed consent, and I have to tell them what the risks/benefits alternatives are in the procedure, and I try to use the best filter for the patient. And if I'm not aware of what the best filter is when I talk to the patient then I'm not really giving them the information that they need to know to make a decision about whether to have the filter or not." (Jones Trial Tr., 780:17 to 781:5, May 18, 2018, excerpt attached as Exhibit C; *see id*. at 998:4 to 999:5, May 22, 2018 (in response to questions about informed consent, Dr. Hurst testifying about the need for physicians to have detailed information from Bard so that he can "serv[e] as the informant for the patient"), excerpt attached as Exhibit D.)

Finally, in closing arguments, the plaintiffs' counsel have raised the concept of informed consent in relation to failure-to-warn arguments: "Ms. Hudnall agreed that the company's responsible for giving risk-benefit information to doctors and doctors need this information for informed consent and that doctors should be told if Bard knew that the filters were tilting. So, again, all of this gets incorporated into the information that Bard should have provided and there's no evidence that they did provide to any doctor, let alone Dr. D'Ayala." (Booker Trial. Tr., 2396:9-15, Mar. 28, 2018, excerpt attached as Exhibit E.)

ARGUMENT AND CITATION TO AUTHORITY

The only claims that remain to be tried concern the design of the Bard G2®X and/or Eclipse® Filter, and Bard's actions concerning the design of the G2X and/or Eclipse Filter.[2] Under Wisconsin's product liability statute, Wis. Stat. sec. 895.047(1)(a), a manufacturer is liable for defective design "if the foreseeable risks of harm posed by the

[2] Although the plaintiffs' negligence per se claim is still pending, the Court has found that the plaintiffs cannot establish that any failure to warn proximately caused their alleged injuries. Thus, the plaintiffs' negligence per se claim must fail for this same reason to the extent that it is based on an alleged failure to warn.

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product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Likewise, the plaintiffs' negligence-based design claim concerns whether Bard "breach[ed] the duty of reasonable care in designing" its Filters. *Nationwide Agribusiness Ins. Co. v. Meller Poultry Equip., Inc*., No. 12-C-1227, 2015 WL 998331, at *3 (E.D. Wis. Mar. 5, 2015). What information physicians need to know from medical device manufacturers in order to obtain informed consent, however, has nothing to do with design issues. As defined by the *AMA Code of Medical Ethics, AMA Ethics Opinion* 8.08, and *ACR-SIR Practice Guideline on Informed Consent for Image-Guided Procedures* (as cited by the plaintiffs' experts in their Rule 26 Reports), informed consent solely concerns the passage of information from physician to patient to obtain the patient's authorization and agreement to undergo a medical procedure. (Ex. A, Drs. Kinney, Roberts, and Kalva's Rep., at 10; Ex. B, Dr. Hurst Rep., at 7.) What information physicians require to engage in the informed consent process has no tendency to make a fact of consequence in determining the plaintiffs' design-related claims more or less probable than it would be without the evidence. F.R.E. 401. As such, opinions about what information is needed to obtain informed consent are irrelevant to the resolution of the plaintiffs' design-related claims.

Rather, what information is needed to obtain informed consent is relevant (if at all) to the plaintiffs' failure-to-warn claims. And the Court has already ruled that the plaintiffs have failed to prove that any alleged failure to warn proximately caused their injuries. Indeed, the Court touched on informed consent in its Summary Judgment Order in this failure-to-warn context: "Plaintiffs identify no evidence suggesting that Mrs. Hyde would have chosen not to receive a G2X filter had she been informed the device had an increased risk of adverse events relative to other IVC filters." (Or. (Doc. 12007), July 26, 2018, at 15.) Thus, the way that informed consent has been presented in this case is limited to failure-to-warn concepts.

For each of these reasons, the Court should exclude opinions about what

information is necessary to obtain informed consent.

RESPECTFULLY SUBMITTED this 10th day of August, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of August, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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